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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,598	03/29/2001	Thomas M. Jessell	57477-A-PCT-US/JPW/MVM	5690
7590 02/11/2004			EXAMINER	
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			CARLSON, KAREN C	
			ART UNIT	PAPER NUMBER
			1653	
			DATE MAILED: 02/11/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/820,598	Applicant(s) JESSELL ET AL.	
	Examiner Karen Cochran Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,38,45,48-50,52,60 and 125-130 is/are pending in the application.
- 4a) Of the above claim(s) 38,129 and 130 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 126 is/are allowed.
- 6) ☒ Claim(s) 27,45,48-50,52,60,127 and 128 is/are rejected.
- 7) ☒ Claim(s) 125 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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Applicant's election with traverse of Invention II, Claims 27, 48, and 125-128, in the paper filed November 17, 2003 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search methods of treatment using the nucleic acid encoding MNR2 and antibodies against MNR2. This is not found persuasive because the method of Claim 38 utilizes a different product, that is the nucleic acid encoding MNR2, and is therefore patentably distinct. The antibodies of Claims 129 and 130 are different products.

Upon examination of the MNR2 protein, the full-length MNR2 protein is allowable. Therefore, the Examiner has examined the methods of treatment utilizing the MNR2 protein, Claims 45, 49, 50, 52, and 60, in accordance with *In re Ochiaie*.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26, 28-37, 39-44, 46, 47, 51, 53-59, and 61-124 have been canceled. Claims 38, 129, and 130 has been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 27, 45, 48, 49, 50, 52, 60, and 125-128 are under examination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27, 45, 48, 49, 50, 52, 60, 127, and 128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is not comprehensible. It is not clear what a homeobox motor neuron restricted pattern protein is. The acronym MNR2 is used, making this name unclear. MNR2 is not defined by structure or by function. Thus, the protein is not defined such that one skilled in the art could recognize the limitations of the claim. See also the dependent claims.

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In Claim 45, it is not clear how only a single somatic motor neuron will be affected by the systemic administration of MNR2. Also, what is the somatic motor neuron being differentiated into?

In Claim 49, it is not clear what abnormality is associated with a lack of one or more normally functioning motor neurons. Also, the phrase "effective to a generate" is awkward. See also Claim 50, 52.

Claim 50 is indefinite because the neurodegenerative disease is not stated. Claims 52 and 60 also lack specific diseases to be treated.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 127, and 128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide written description of mouse, rat, or human MNR2 protein.

Claim 27, 45, 48, 49, 50, 52, 60, 127, and 128 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MNR2 comprising SEQ ID NO: 1, does not reasonably provide enablement for all MNR2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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In *Ex parte Forman* (230 USPQ 546) the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation:

1) Quantity of experimentation necessary: It would require undue experimentation to acquire all MNR2 across all species, to the scope of the claims.

2) Amount of direction or guidance presented: At page 45 and 47+ of the specification, routineers in the field are invited to find for themselves, the scope of the MNR2 proteins as claimed, via nucleic acid probes, or antibody assays.

3) Presence or absence of working examples: None.

4) Nature of the invention; 5) State of the prior art; 6) Relative skill of those in the art: The invention is highly technical and the MNR2 protein is not recognized in the prior art. Those working in the art are highly skilled.

7) Predictability or unpredictability of the art: Finding a protein that is involved in the differentiation of neurons is highly unpredictable.

8) Breadth of the claims: The claims are very broad.

For all of these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

Claims 45, 49, 50, 52, and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These Claims are drawn to methods of treating neurological diseases/injuries by administering the MNR2 protein systemically to a subject, thus causing differentiation of neuronal precursor cells.

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Simply, these methods are not art-recognized such that there could be a nexus between other prior art proteins and the treatment of neurological diseases/injury and MNR2.

In *Ex parte Forman* (230 USPQ 546) the Board considered the issue of enablement in molecular biology. The Board held that the following factors should be considered to determine whether the claimed invention would require of the skilled artisan undue experimentation:

1) Quantity of experimentation necessary: It would require undue experimentation to determine how one would treat diseases/injuries that are not known to be routinely treatable with a new protein that is involved with neuronal cell differentiation.

2) Amount of direction or guidance presented: Page 50+ provides a generic discussion of methods of treatment using protein, and these methods are not specific to neural abnormalities.

3) Presence or absence of working examples: None.

4) Nature of the invention; 5) State of the prior art; 6) Relative skill of those in the art: The invention is highly technical and the MNR2 protein is not recognized in the prior art. Those working in the art are highly skilled.

7) Predictability or unpredictability of the art: Finding a protein that is involved in the differentiation of neurons is highly unpredictable; using the protein to differentiate neuronal cells in vivo is highly unpredictable.

8) Breadth of the claims: The claims are very broad.

For all of these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention.

Claim 125 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

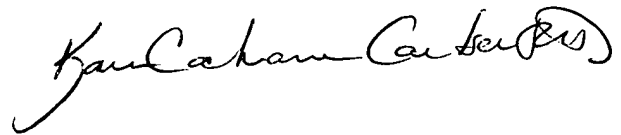
Claim 126 is allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read "Karen Cochrane Carlson (Ph.D.)". The signature is fluid and cursive, with the initials "Ph.D." circled at the end.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER